

**Comparative analysis of market-based health delivery models
in rural India**

By

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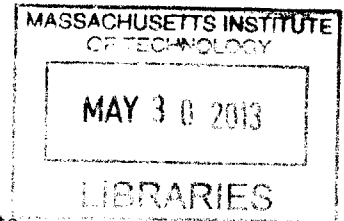
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ABSTRACT

The rapid economic growth in India and accompanying demand for improved healthcare, particularly in rural populations, make a compelling case for global pharmaceutical companies to develop new business models to serve these underserved markets. Increasing competition in developed markets and an impending “patent cliff” add pressure to derive innovative approaches to opening new revenue channels. To do so in base of the pyramid markets, firms will need to overcome substantial infrastructure and financial challenges, and navigate a complex ecosystem made up of public and non-profit entities as well as experienced Indian generics manufacturers.

This paper describes specific methods being employed by global pharmaceutical manufacturers in rural Indian markets, and analyzes them not only on the basis of sustainability and scalability, but also on the value delivered to the consumer, using Michael Porter’s value-based approach to global health delivery. The analysis reveals an opportunity for these companies to expand their reach along the whole health delivery chain, and recommends both short- and long-term strategies that can be employed for them to do so, in a financially sustainable way.

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1 Pharmaceutical Industry and Global Health

There may be no industry more conducive to public-private partnerships than pharmaceuticals. This complex industry relies on private players, incentivized by profit, to develop life-saving drugs. These products are traditionally distributed in silos through exclusive relationships with various distribution channels (e.g. doctors, pharmacies, hospitals). Patent protection guarantees certain margins over the duration of that patent. Once the patent expires, generics manufacturers are able to copy the drug and distribute for much lower prices. This cycle repeats, with global pharmaceutical manufacturers relying on innovation and higher-margin patented drugs to derive profits, and generics competing in a much more commoditized market once that patent expires.

The situation becomes complex when it comes to the treatment of patients in developing countries, where prevalence of life-threatening illnesses, including HIV/AIDS, malaria and TB, is distinctly higher than in developed countries. People living in these parts of the world do not have the means to purchase these drugs, regardless of whether they are under patent or not. As a result, global health-focused organizations leverage donor dollars to subsidize the costs of delivering these drugs to the people who need them most. Country governments also attempt to subsidize the cost of delivery through their own programs. Mechanisms are put in place by international entities to incentivize drug manufacturers to distribute their drugs in these underserved markets. But ultimately their decisions are driven by the need to generate profits, and appease shareholders.

However, as developed markets become increasingly saturated and general state of health continues to improve, pharmaceutical companies are starting to look for ways to profit in new markets, as we will see in this thesis. Rapid growth in population in developing countries and the consistent need for treatment of deadly but treatable diseases, including malaria and TB, provide an attractive new market opportunity for growth. As a result, more pharmaceutical companies are looking to build partnerships and distribution channels that will allow them to profitably serve developing countries. This requires addressing a host of new challenges, including a shift from a “low volume, high margin” business to a “high volume, low

margin” one, meeting guidelines set by the World Health Organization (WHO) and individual countries, overcoming physical infrastructure gaps, competing with the informal market and high prevalence of counterfeit drugs, and creating demand for drugs in an uninformed and uneducated market that cannot be reached through traditional marketing and sales channels. But for those that choose to challenge their traditional mode of business, huge opportunity awaits. India is one example of such an opportunity, and is among the most attractive in the world. But with the long-standing expertise and domination of its domestic players, and the ineffectiveness of its public health system, the country presents a unique set of challenges that need to be addressed.

1.1 Thesis Motivation

India’s pharmaceutical industry ranks among the top five in emerging markets in terms of size. In 2013, the sector achieved \$19 billion USD in sales in 2009, and is projected to grow to \$74 billion USD in sales by the year 2020. It is the third largest market in the world by volume, and the 14th largest by value. At the same time, poverty levels in India are striking. The country is the second-largest market in the world with a population of 1.24 billion and an average per capita income of approximately \$3,200 USD at purchasing power parity (PPP). Though the economy is advancing quickly, the country is also home to a third of the world’s poor. World Bank estimates in 2010 put 32.7% of the population below the international poverty line of \$1.25 USD per day, and 68.7% on less than \$2.00 USD per day (World Bank 2013).

The juxtaposition of these two facts creates a tension that is the focus of this paper. Given the growing demand for healthcare in India, and the poor availability in rural settings, pharmaceutical manufacturers are actively seeking new models that will allow them to succeed in these new markets. The rapidly changing landscape of healthcare and pharmaceuticals in India makes it difficult to track the approaches being attempted by these for-profit players. The purpose of this paper is to discuss the need for new approaches to healthcare in impoverished Indian markets, and to provide an argument for pharmaceuticals to assume a larger role in healthcare delivery than they traditionally do in developed markets. This will be

done by identifying some of the changes that have been taking place in the Indian pharmaceutical industry as both profit-oriented companies and socially oriented organizations look to increase access to medicines in rural markets, and to analyze their sustainability and scalability based on the challenges they pose both to the other players in the ecosystem, and to the organization itself. The effectiveness of these models will also be considered based on the benefit to the end-consumer.

1.2 Thesis Methodology

This thesis was borne from a deeper interest in challenges facing multinational businesses looking to penetrate impoverished markets, with a specific interest in rural areas. The original intention was to compare the microfranchising approaches being used by Novartis in their Arogya Parivar model, and by Unilever with their Shakti project. It became apparent through industry research however, that the pharmaceuticals and consumer goods industries were subject to such different regulations in India, that a comparison between their models would yield only general findings and unrealistic recommendations for the businesses.

Further research into the pharmaceuticals industry in India revealed compelling indicators of a changing landscape as the country transitioned from developing to developed, and regulations on foreign investment and patent recognition were shifting. Complementary to this was an increasing focus on the spending power in Tier 2 and rural markets. As a result, global pharmaceutical companies were testing innovative approaches to India's rural markets. Three models were chosen that best highlighted the different options from the corporate side.

Even with a comprehensive understanding of each of these business models, it was unclear whether access to drugs alone was enough to drive improved health outcomes. For that reason, the analysis focused not only on comparing strategies for overcoming challenges for multinational business in impoverished markets, but also on the ability to effect health delivery. This was done specifically through the lens of Michael Porter's value-based approach to healthcare delivery. The analysis revealed several opportunities for global pharmaceutical companies to expand their market reach by addressing other

aspects of health delivery that are lacking in rural markets. The resulting recommendations are aimed at incenting these companies to invest in the long-term improvement of healthcare in these underserved markets, and presenting actionable short- and long-term approaches that could be used to do so.

The literature search was completed using published materials made available from various news publications, academic and corporate sources, as well as papers from third-party organizations, such as the WHO and World Resources Institute (WRI). In-depth research on specific corporate business models was conducted using official published articles, and supplemented with interviews with Anuj Pasrija, Head of the Social Business Group at Novartis, Meghdoot Deherkar, National Sales Manager for Arogya Parivar at Novartis, and Clifford Samuel, Vice President of Access Operations & Emerging Markets at Gilead Sciences, Inc.

1.3 Study Limitations

As this paper focuses heavily on delivery models and the global health supply chain, we have chosen to focus only on prescription drugs that would be distributed through a similar supply chain. Vaccines are not included here because of the further complications in their supply chain due to complex transportation and storage requirements. Over-the-counter (OTC) drugs are excluded for the opposite reason: lack of regulation requirements and simplicity in handling make them more akin to consumer goods. The focus exclusively on prescription drugs is made with the intention of exploring and suggesting as tangible strategies as possible.

2 Introduction to Base of the Pyramid Markets

According to a report by the WRI and International Finance Corporation (IFC), the Base of the Pyramid (BoP) is defined as those living with annual incomes below \$3,000 USD in local purchasing power. In India specifically, this amounts to less than \$1.56 USD per day. Individually, these BoP consumers have considerably less spending power compared to the world average. Together however, they constitute a \$5 trillion USD global consumer market (Hammond, Kramer et al. 2007). This cumulative spending power is only one reason why corporations have started to explore ways they can tap into this previously ignored consumer base. Doing so requires challenging existing business models and applying innovative approaches to understand and succeed in an entirely new market.

2.1 Living Standards and the “Poverty Penalty”

Typical BoP households are subject to adverse living conditions. They lack access to basic services, including water and sanitation, electricity, and basic health care. Households allocate the majority of their budget to food and housing. Shockingly, half of health spending goes towards pharmaceuticals, suggesting that traditionally, access to drugs is extremely costly (Viswanathan 2011).

Access to modern financial services is severely lacking in BoP markets, owing mostly to the lack of formal land ownership and informal means of living, lack of official identification, and balances far below the necessary minimum for formal banks. Coupled with the significant distances that often need to be travelled to reach banks that are located in cities, people in BoP markets are discouraged if not prevented from accessing basic financial services.

Most BoP consumers also lack access to organized markets where they can formally sell and buy necessary goods. As a result, they are subject to informal means of accessing buyers and sellers, including local employers and exploitative middlemen. These middlemen often ask for unreasonably high rates for their services, forcing BoP consumers into a cycle of subsistence living, with no opportunity to generate enough income to move up the economic pyramid. This cycle of purchasing necessary goods for higher prices and being only able to afford enough to survive is known as the “poverty penalty”. Adding to this

cycle is the fact that a highly dispersed customer base means these markets are not able to realize the economies of scale and bargaining power of developed and more organized markets. As a result, their per unit purchasing costs are higher.

For BoP consumers to be able to move into a higher income bracket, they must have the opportunity to generate and save additional income. As discussed in following sections, some corporations are looking at long-term opportunities to invest in the economic advancement of these markets, with the objective of achieving profits when they are able to do so.

3 Multinational Business at the Base of the Pyramid

Traditional business thinking has been challenged by the notion of business at the BoP. In 2004, C.K. Prahalad published his now famous work, “The Fortune at the Bottom of the Pyramid”. In it he introduces the disruptive notion that there are actually profits to be won from the most impoverished communities. He places the onus on businesses to drive radical innovation in their business models to derive profitable ways of delivering goods and services to the poor that will allow them to escape poverty (Prahalad 2006). In doing so, he claims that businesses can tap into enormous unrealized buying power. Academics and organizations have built on Prahalad’s ideas, suggesting strategies and frameworks that corporations should employ to increase their odds of success at the BoP. Notable papers are summarized below. Their strategies are used to develop the thesis’ framework for evaluating strategies of pharmaceutical manufacturers at the BoP.

3.1 Building Better Business Ventures with the Base of the Pyramid

Several companies have attempted to serve base of the pyramid markets, though with varying levels of success. In his article in “Next Generation Business Strategies for the Base of the Pyramid” (London & Hart, 2011), Hart argues that managers working in the BoP must:

1. Design based on creating market opportunities and crafting solutions with the BoP;
2. Pilot by orchestrating effective experiments and managing failures; and
3. Scale through generating co-mingled competitive advantage, as well as leveraging and transferring social embeddedness.

His arguments focus on the idea of creating “mutual value”, which refers to improvements in the quality of life of the BoP communities, as well as financial value for the business. Much of that value is realized by creating a market in the first place, by increasing demand, reducing costs and developing public goods. For example, customers may need to be educated on the importance of cleanliness to be willing to spend

on products like soap or detergent. They also need to have the income required to purchase these products.

According to Hart, a critical part of succeeding at the BoP is building strong and sustained relationships with the communities; trust and mutual respect are critical, and require significant time investments. As mentioned in a previous section, due to a lack of infrastructure and support, BoP communities are often forced to access goods and services through both informal and formal economies. Businesses are thus required to interact with both of these economies, to identify and strengthen the best platform for growth. Strategies could include tapping self-organized community groups, informal leaders, and physical infrastructures, amongst other existing assets.

Given the strong development implications of these relationships, it is often the case that they are managed by public sector or non-profit organizations that place emphasis on social goals. Businesses looking to tap into these relationships will need to show a willingness to align with these goals as well. This could very well include financial investment into the growth of these different platforms for reaching impoverished communities. While these may be perceived as “sunk costs”, the good faith developed between the business and the organization can lead to strong in partnerships and exclusive access in the future.

3.2 The Next 4 Billion

In 2007, the WRI and IFC jointly published a paper describing the situation of BoP economies around the world, and the promise shown by market-based solutions to circumvent the long-standing challenges faced by traditional development approaches in scaling and sustaining solutions to poverty. They stress the importance of challenging traditional approaches, including direct public investments, subsidies and/or handouts, and praise market-based approaches for their ability to innovate, compete, and improve efficiency in reaching the BoP. The report recommends four successful strategies have been used both exclusively and in parallel in many BoP enterprises (Hammond, Kramer et al. 2007):

1. **Focusing on the BoP:** creating unique offerings that specifically address the needs and wants of the market. For water access this might include point-of-use systems, whereas for finance this may include microfinance options. These specifically developed products and services are more suited to those living in poverty, and acknowledge many of the constraints that are not seen in developed markets.
2. **Localizing value creation:** redistributing along the value chain to favor those closer to the end consumer. This could be done through microfranchising, and/or localized supply chains and sales channels. These usually involve significant investment in training and capacity building in the communities. This approach has been especially popular in product sales ranging from healthcare (e.g. Living Goods) to food.
3. **Enabling access:** employing novel distribution channels, financially and physically, to reach consumers. This could include new small-packaging strategies, tiered financing, and deployment of low-cost technologies.
4. **Unconventional partnering:** working with atypical third parties to bridge infrastructure, funding and knowledge gaps. These partners could include government and NGOs, among others. This approach has been pursued successfully in many industries including energy, transportation, health care, financial services, food, and consumer goods.

Overall the paper endorses the notion that BoP markets can only be reached by developing unique offerings that not only address their individual needs and livelihoods, but also address the infrastructural challenges that are beyond their control.

3.3 Short- vs. Long-Term Tradeoffs

Overall, strategies focused on the BoP revolve around an investment in the short-term, in favor of building a consumer base for the long-term. Empowering the consumer and enabling local development are keys to setting a foundation for scalable and sustainable business growth. The literature suggests that the willingness to ride out uncertainties in new markets is rewarded with trust and relationships that span

the long-term, and are critical for enabling market development. It is only when the markets become more developed and affluent that a short-term perspective and competitive focus on profitability becomes viable. This notion will reappear later in the thesis, when we discuss the tradeoffs between the approaches being used in the pharmaceuticals sector, and offer strategies for how they might build a long-term competitive advantage.

4 India's Healthcare Sector

The healthcare sector in India is experiencing rapid growth. Between 2000 and 2009 the industry, which includes delivery services (hospitals, clinics) and related services (pharmacies, diagnostic centers) grew at 9.3% and was expected to reach revenues of \$77 billion by 2012, according to a 2010 report by strategy consulting firm PricewaterhouseCoopers (PwC) (PricewaterhouseCoopers 2010). The country also leads the world in number of diabetics and heart patients, and is near the top for cancer.

The population of the country is fairly young, with 50% under the age of 30. Currently, 80% of doctors in the country live in urban areas, while 70% of the population still resides in rural parts. As a result, key players are exploring opportunities to bring healthcare to the rural interior, including the use of technology, and public-private partnerships to help with infrastructure development (Chandrasekhar, 2011).

An inefficient and unreliable public healthcare system means that most people in India choose from the numerous private healthcare providers instead. In fact, nearly 70% of health expenditure in the country is spent on private providers, of which 86% is out-of-pocket (World Health Organization 2012).

4.1 Structure of Healthcare System

Due to years of underfunding, the public health system in India has become notoriously ineffective. Not only are most public health facilities limited to primary care, but roughly 75% of the medical facilities, including pharmacies, are located in urban areas, leaving rural areas underserved.

The government has made efforts in recent times, to respond to this imbalance. Government spending has been increased from 1% GDP to 2 to 3%, and new policies have been introduced to encourage capacity building, both in terms of physical sites (i.e. hospitals) and people (i.e. training for medical practitioners). The government also introduced a health insurance scheme in 2009, to curb out-of-pocket spending in the private sector for Indians living below the poverty line (BPL). The scheme provides \$745 USD for every BPL worker and his or her family in the informal sector. The plan was also extended to those covered by the NREGA (National Rural Employment Guarantee Act), who have worked more than 15 days in the

preceding fiscal year. Spending on the National Rural Health Mission (NRHM) also increased by 15% from 2010 to 2011, to \$2.92 billion USD. To encourage the development of healthcare services in poorer areas specifically, the government announced in its last Union Budget, a tax exemption for hospitals built in Tier 2 and Tier 3 cities (PricewaterhouseCoopers 2010).

4.2 India's Pharmaceuticals Sector

4.2.1 Pharmaceuticals Supply Chain/Retail Channels

The pharmaceuticals supply chain is become an increasingly important and competitive element in the Indian market. Companies are looking to reach into new markets and to develop customized supply chains that can reach more customers.

The reasons for this shift are multiple. First, the general income levels of Indians are rising. In cities and among wealthier Indians, this is paired with demands for improved healthcare services, and increased demand for branded drugs. According to a report by McKinsey & Company, the three categories of pharmaceuticals players (large domestic players, small to mid-size domestic players and large multinational companies) are experiencing different rates of growth. Large domestic players are growing with the market, smaller domestic players are growing ahead of the market, and large multinationals are lagging behind. Given these trends, they expect that priorities for each will differ significantly. For large domestic players, the challenge will be to maintain their position as market leaders in face of increasing competition. For small to midsize players, the challenge will be to maintain their performance standards ahead of the market, while addressing issues of scale and increasing complexity. For multinationals, the challenge will be to maintain relevance in the market, despite patent uncertainty (Kumra, Mitra et al. 2005).

The underserved rural and semi-urban markets are also becoming increasingly attractive and competitive, as they present a new market opportunity for global pharmaceutical companies and local generics manufacturers. The report by McKinsey and Co. projects that the rural and Tier 2 markets (made up of cities with populations below one million) will make up 45% of the market for pharmaceuticals in India

by 2015. The rural market is expected to contribute 27% of that, while Tier 2 markets will make up the remaining 18%. This is comparable to the 25% expected contribution from Tier 1 markets (Class I and IA cities) and 30% from metros. In contrast, only 20 to 30% of the pharmaceuticals sales force is deployed in Tier 2 markets (Kumra, Mitra et al. 2005). This growth in demand for medicines is mirrored on the quality side as well. As the income and consumption levels in these Tier 2 markets rise, so will their demand for quality healthcare. As a result, these players are exploring new approaches to distribute their products to these markets. As we will see in the paper, developing a customized supply chain that can respond to differences in product requirements, pricing and sales coverage is only one way that pharmaceutical manufacturers are responding to these market changes. Other strategies include partnering with other players to leverage different expertise, or moving into a domain typically occupied by other players, who are also described later in the paper.

4.2.2 Additional Challenges for Global Pharmaceutical Manufacturers in BoP Markets

Despite the efforts of the Indian government, non-profits and multilateral organizations, much of rural India remains out of reach. As the markets move forward and incomes rise, the private sector players start to show more interest in tapping these markets, and have the capacity and capital to try new innovative approaches to do so. Other than the market-driven factors described in the sections above, global pharmaceutical manufacturers are also facing industry challenges that will threaten their businesses in the near future. In 2015, the pharmaceutical industry is poised to hit a “patent cliff”, when many of their patents will expire, opening these drugs to Indian generics manufacturers and others. Together they are poised to lose \$118 billion in revenue (PricewaterhouseCoopers 2010). Generics manufacturers are ready to reap the benefits of this shift in dynamic, and at the same time are looking to leverage a huge local scientific community to integrate upstream into drug discovery and development. This double threat is increasing pressure to develop and secure carefully crafted partnerships, innovative business models, and strategies for reaching new markets.

To compete in BoP markets, global pharmaceutical manufacturers will need to overcome considerable challenges, and completely transform their business model from “high-margin, low volume” to the inverse. They will also need to anticipate and react to competition from generics, which would typically not be the case in developed markets. But in the hopes of providing access to medicines to these impoverished populations, several social players have intervened, to manipulate the rules of the market and provide access to all levels of the economic pyramid. Some of these interventions, including the flexibility in patent enforcement, are described below.

4.2.3 Comparison of Branded and Generics Drug Manufacturers

Typically, generics manufacturers are permitted to produce and market a drug once its 20-year patent has expired. The advantages of generics drugs over branded are multifold. First, from a purely pricing perspective, generics can price drugs much cheaper since they do not require the overhead to invest in new research opportunities. The generics industry is also more competitive by virtue of having no patents, meaning manufacturers must come up with innovative ways to lower their costs to compete in the market. The typical response of global pharmaceutical manufacturers has been to apply a deep discount to their medicines in developing countries, such that they are priced similarly to the generics. Price data gathered by Médecins Sans Frontières (MSF) in 2003 showed that branded drugs might even cost less than their generic counterparts (MSF 2003).

Another benefit of having drugs off patent is that it allows generics to combine multiple medicines that were previously patented by different companies into a single fixed-dose combination (FDC). This makes the administration process much simpler for healthcare providers and patients. Despite these advantages however, even generics are still financially out of reach for most of the rural poor. Social players attempt to fill this gap by using donor-funded approaches, including those described below.

4.2.4 Influence of Social Players and Regulation in the Pharmaceuticals Market

Adding to the inherent competitiveness of the relationship between patented and generics manufacturers is the role of social players and regulations. Based on the urgency of need and other considerations, third-

party non-profits and multilaterals have the authority, with the consent of the drug manufacturer, to release the patent and open the drug to manufacturing by generics. This understandably adds considerable complexity to the medicines supply chain, and to the market as a whole. The interplay of private sector sellers and public sector and non-profit buyers using subsidies and other sources of financing distorts the market, making it difficult to evaluate its true value.

4.2.4.1 Doha Declaration on TRIPS Agreement and Public Health

In 1994, the World Trade Organization (WTO) established the *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS), to set minimum standards for the protection of intellectual property (IP). Arguing that the interpretation of TRIPS was too narrow in developed countries, developing countries pushed for realignment during the WTO Ministerial Conference in Doha in 2001. The result was the *Doha Declaration on the TRIPS Agreement and Public Health*, which stated that “[the] Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all (World Trade Organization 2001).” Interpretations by developing countries can lead to, among other employable tools, compulsory licensing and parallel importing.

Compulsory licensing allows the governments of countries to allow for the production of generics for a drug still under patent, without the patent holder’s consent. Certain conditions govern the use of compulsory licensing. For example, there must have been reasonable attempt at striking an agreement with the patent holder by regular commercial means. Patent holders are also still required to be compensated in some way.

The government of India followed this interpretation until 2005, when it applied a Patents Act that extended patents, in line with the TRIPS Agreement, to pharmaceuticals and agricultural chemicals. This partly explains the motivations for global pharmaceuticals manufacturers to expand their reach in the country, but its interpretation is still loose. Recent cases, including the rejection of Novartis’ patent

application for a new version of its cancer drug, Gilvec, highlight the lack of consistency in the interpretation and application of this new law (BBC News Business 2013).

Parallel importing allows governments to import patented versions of a drug that have been manufactured and sold in another country. This means that drugs sold for a lower price in other countries can be imported, without the consent of the patent holder. The legal justification behind this action is known as *exhaustion*: that the patent holder has already been compensated through the sale in the originating country, and no longer holds rights over those drugs (World Trade Organization 2006). In order to regulate this practice, countries have enacted import permits, which only allow for specific amounts of drugs to be imported for specific purposes.

4.2.4.2 Medicines Patent Pool

UNITAID, a global health financing mechanism, established the Medicines Patent Pool in July 2010, with the objective of releasing patents for HIV drugs. The organization leverages existing WHO guidelines, including the prequalified medicines defined later in the paper, to guide decisions on which drugs to pursue. They then enter into negotiations with the patent holders to obtain the rights to release their patent. Once an agreement has been struck, generics manufacturers, many of whom are Indian, can obtain a license to develop, produce and sell the drug in the agreed upon countries. The patent holders are compensated with a small royalty on the sales of these generics (Medicines Patent Pool 2013). So far, the Medicines Patent Pool has been able to strike agreements with Gilead Sciences and ViiV Healthcare (an alliance of GSK and Pfizer), both of whose business models are described in detail in section 0, to release patents for their HIV drugs.

5 Stakeholder Mapping

Given the high complexity of the medicines distribution ecosystem in rural India, it is helpful for this analysis to map out each of the players, and to list their role in the distribution chain, as well as their motivations and priorities. Doing so will help us to understand the nature of their relationships to each other, from which we can infer how global pharmaceutical manufacturers might be able to leverage their strengths to extend their distribution channels in rural markets.

5.1 International Procurement Agencies

Organizations in this category include the Clinton Health Access Initiative (CHAI), and the Bill & Melinda Gates Foundation, among others. These organizations are funded by philanthropists and other international funding organizations (described below), and work to fill the gaps in the global health distribution chain, particularly between global pharmaceutical companies and ministries of health in developing countries. CHAI increases its bargaining power with the drug providers by collecting the demands of several countries, and negotiating for lower prices based on high volumes. They work only with governments where they have been invited, and take on specific projects that, in most cases, are defined with an end-objective that will signal the end of the engagement, such as number of cases successfully treated. Using these objectives as their goal, CHAI works with the government to define the right steps to take so that the process can be sustained once they leave. For example, CHAI will aim for a drug price that is affordable, but not so heavily subsidized such that governments will not be able to match the difference without their support. Their objective is to become redundant, and to build support networks for medicine distribution that are supported by the public health sector (Clinton Health Access Initiative 2013).

5.2 Multilateral Organizations

Multilateral organizations invested in global health include the WHO, the World Intellectual Property Organization (WIPO) and the WTO. These entities work to regulate the global health sector, and to lower

barriers to access for populations in developing countries. They negotiate with global pharmaceutical companies to forgo their patents for a royalty through programs like the Medicines Patent Pool, and regulate which countries can produce generic versions of drugs still under patent elsewhere. The WHO also publishes a list of Essential Medicines and Prequalified Medicines (PQM), which governments often use to guide purchasing and distribution decisions in their own countries.

5.3 International Funding Organizations

One of the most significant gaps in the global health ecosystem is financing. Even at generic prices, many medicines are still out of reach for BoP consumers and providers. International Funding Organizations such as The Global Fund and UNITAID fill these gaps by providing funding to international NGOs, and to governments looking to implement new programs. Both The Global Fund and UNITAID are entirely donor funded(The Global Fund 2013, World Health Organization 2013). These organizations focus on treatment for the diseases traditionally perceived as most critical, namely HIV/AIDS, TB and malaria.

5.4 Global Pharmaceutical Companies

In this category belong the for-profit companies who are responsible for the development of the drugs themselves. Examples include Novartis, Pfizer, Gilead Sciences Inc. (Gilead), GlaxoSmithKline (GSK) and others. Typically, these companies compete to develop new and more effective drugs, which are then protected by patent for 20 years. The profits generated through the sales of their branded drugs are invested into the R&D for new drugs. As with most traditional private-sector companies, these pharmaceutical players are driven to maximize shareholder value. Therefore, they tend to compete on the bases of innovation in R&D and drug development, and in their marketing and sales channels.

5.5 Generics Manufacturers

The domestic market for generic drugs in India is intensely competitive. This is owing to regulation established in 1972, which allowed companies to manufacture generic versions of patented drugs, so long as a different manufacturing process was used. As a result, Indian pharmaceutical companies developed

expertise in reverse engineering drugs and developing copies. They have also established far-reaching distribution networks within the country. This legislation was modified in 2005 to not permit wholesale marketing of generics for drugs still under patent from 1995 onward. However, the industry has not been deterred. Today, India manufactures 20% of generics globally (PricewaterhouseCoopers 2010).

5.6 Public Health System

Medicines can be procured by the government directly by the country's Central Medical Stores (CMS). The CMS are non-profit entities with some ties to the government, putting them in a better position to handle international patent exceptions and negotiations than the international procurement agencies described above. Due to lack of funding however, the CMS are often weaker in terms of infrastructure, personnel, and medical expertise (Sullivan, Goentzel et al. 2011).

5.7 Private Healthcare Providers

Lastly, perhaps in response to the inefficiencies in the public sector, private healthcare has become the dominant alternative, and in some cases the only alternative, for most Indians. The private healthcare sector in India is massive. Private healthcare providers can be funded by donors, but often rely on paying customers to fund their business. They exist at all levels of the healthcare pyramid, and the socio-economic pyramid.

As the forces discussed in earlier sections change the landscape of the pharmaceuticals market drug delivery in India, the role of each of these players is likely to change as well. In the following sections we will focus in on the global pharmaceuticals companies, and discuss some of the approaches they have taken to extend their reach in the country. As we will see, accounting for the motivations of each of these other stakeholders is critical in designing an effective strategy for sustainable expansion.

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6 Traditional Partnership Models for Pharmaceuticals in India

6.1.1 Mergers and Acquisition

The traditional form of partnership between global manufacturers and generics has been through merger and acquisition. Examples of recent acquisitions include Abbot's purchase of local company Wockhardt for \$350M USD in 2011, and Reckitt Benckiser's acquisition of Indian generics manufacturer Paras Pharma in 2010 for \$726M USD (PricewaterhouseCoopers 2010).

Despite their popularity, the limitations of these acquisitions are many. First, as a whole, the availability of assets is decreasing. This means valuations of acquisitions have also risen, and hence become less affordable in the past few years. Second, a full acquisition is limited in growth opportunities down the road. Once acquired, the generic may be challenged to keep pace with the innovations of its local competitors. As a result, new models are emerging that allow the organizations to benefit mutually from each other, and maintain the unique company structures that allow them to be competitive in their own markets.

6.1.2 Alliances and Partnerships

Varying forms of alliances and partnerships offer opportunities for both parties to benefit in ongoing ways. For global pharmaceuticals it offers a connection to local markets, insights into the low-cost manufacturing process, and access to an expansive market. In return, they offer new products and technologies to these booming generics enterprises, as well as access to global markets and global leadership.

For example, Lupin, a for-profit generics manufacturer in India has signed a deal with Eli Lilly to distribute their Huminsulin brand of anti-diabetic drugs in the country. In return, Eli Lilly has agreed to provide a considerable sales force to market their product, and to educate physicians and patients. Bayer Healthcare has formed a 50-50 joint venture with Indian partner Zydus Cadila, to form a new company focused on the Indian Market: Bayer Zydus Pharma. Bayer contributes the sales and marketing

component, while Zydus contributes its women's health products, diagnostic imaging and other products. Sun Pharmaceuticals Industries and Merck & Co have also entered into a joint venture to develop, produce and market innovative generics in India and other emerging markets (PricewaterhouseCoopers 2010).

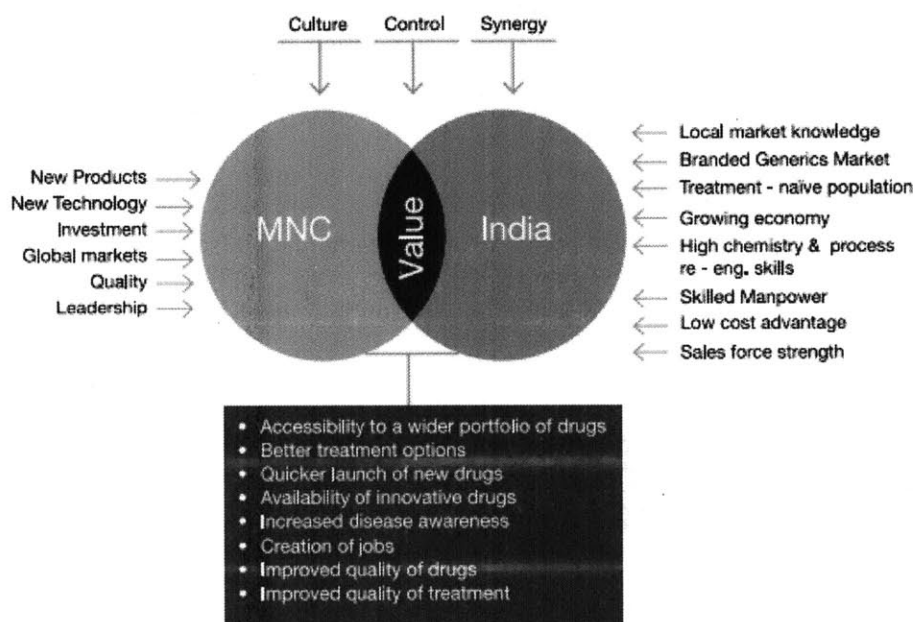


Figure 1: Value of Generic and Multinational Partnerships (Source: PricewaterhouseCoopers 2010)

It is clear that the nature of these agreements can vary significantly, but ultimately they are meant to help both parties improve their current situation. What is unclear from these agreements is whether the end consumer in the rural market also realizes improvements. While pharmaceutical companies have strived to overcome business challenges in reaching BoP markets, there are two important outcomes that are not actively measured in all cases. First, are the products actually making it into the hands of the consumer? Second, are consumers actually seeing improved health outcomes? For these pharmaceutical manufacturers, reaching high volumes is directly linked to a business target and is therefore tracked more actively. Through this comparative analysis however, we will see that not all these manufacturers have the same methods for tracking their performance in this respect. In fact, last-mile delivery and measurement continues to be a challenge. The second question about health outcomes is much more challenging to answer, and not typically within scope of these organizations. We therefore turn to outside

sources for estimates on how health outcomes have improved since some of these programs have been implemented. Through this analysis we will see which of these programs make the greatest contributions, both from the scale perspective (measured in volumes), and the social perspective (improvements in health outcomes).

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7 New Pharmaceutical Business Models in Rural India

The models described in this section illustrate three different approaches that have been taken by global pharmaceutical companies, in an effort to increase their penetration in rural Indian markets. We will see how each company has modified or in some scenarios created an entirely new business model to deal with the specific challenges in this market. For Novartis, Arogya Parivar allows them to build deep connections with rural distributors and consumers, and to offer products specifically catered to their needs. Gilead leverages strategic partnerships with generics manufacturers and international procurement agencies to mitigate their weaknesses in low-cost drug development and demand forecasting. ViiV Healthcare combines the drug development capabilities and capital of two global pharmaceutical companies to invest in relationships with generics manufacturers to lower costs of their drugs, and with local non-profits to raise product awareness. Our analysis in the following section reveals the strengths and weaknesses of each of these approaches, and identifies other opportunities through the lens of impact to the end consumer.

7.1 Individual Efforts: Novartis' Arogya Parivar

Through their Arogya Parivar (AP) project, Novartis aims to serve the BoP in rural India by providing access to drugs and medical supplies, and by building patient awareness in the communities on the importance of healthcare.

Novartis has taken a localized approach to distribution. Each Arogya “cell” consists of approximately 80 villages within in 25km radius, and is managed by a Health Educator and a Sales Supervisor. The Health Educator is responsible for raising patient awareness. He or she holds two health meetings per day, attracting approximately 140 patients. These meetings serve multiple purposes. In addition to educating patients on diseases and available treatments, they also serve to monitor drug compliance from patients already on treatment. The Health Educator is also able to sell over-the-counter (OTC) drugs, and can issue patient referrals to specific doctors. He or she travels between villages by foot, bicycle, or other local means.

The Sales Supervisor takes on more advanced tasks. Travelling by van, he or she conducts “Health Camps”, using audio and video support. The Supervisor attracts local doctors and pharmacists, who learn more about Novartis’ product offering, and can sign up for loans to purchase new offerings. The Supervisor also builds partnerships with these doctors for patients referred through the Health Educator program.

Using this model, AP has achieved profitability within 3 years of operation, increasing sales 25 times since 2007 (Novartis 2012).

7.1.1 Arogya Initiative Framework

The AP project is structured around meeting four objectives for the BoP consumer: Awareness, Adaptability, Accessibility and Affordability. These four objectives not only reflect the social mission of the program, but also acknowledge the need for targeted business marketing and product development, in order to achieve sustainable business returns from their target market.

7.1.1.1 Awareness

Novartis recognizes that a critical component to the project’s success is demand from the consumers for their goods and services. To that end, they have strived to educate the patients on disease and treatment through their Health Educators, and have built brand recognition and understanding of their product portfolio amongst physicians through their Sales Supervisors.

7.1.1.2 Adaptability

For a product to be accepted by consumers, it must be able to address their specific needs at an affordable price. To meet this constraint, Novartis has developed a customizable portfolio of drugs that can be pieced together to meet the individual needs of each doctor. Some of the products offered in this portfolio include TB treatment, antibiotics, nutritional supplements, GI, general painkiller and calcium supplements, among others. Each of these products is also translated into the local language.

7.1.1.3 Accessibility

Novartis' uniquely developed distribution network allows it to tap into previously unreached rural communities. They have also set up local sub-distributors to enhance the supply chain in these areas.

7.1.1.4 Affordability

Finally, in order for each patient to be able to afford Novartis' products, the company uses low-unit-price packs (LUPs), where smaller quantities of products are sold in separate packaging, at a lower price point. This format is more affordable to lower-income consumers, and hence helps to increase consumption. Novartis' goal is to keep weekly treatments below \$1.25 USD.

7.1.2 Sales Tracking: Referral Cards

One of the newer components of AP's success is the ability to generate additional revenue through increased sales in these new markets. Their business model has been designed to do this specifically through their referral system. Using the Sandoz (referring to Novartis' generics division) referral cards, Health Educators drive new customers to local doctors and pharmacists, who are encouraged to purchase their medical supplies and medicines from Novartis' Sales Supervisors. This virtuous cycle should deliver both social and business value. The actual effectiveness of this system however, is unproven, as discussed in a later section.

7.1.3 Geographic Reach

As of April 2013, Novartis' AP project operates 257 cells in 10 states and 181 districts across India. They employ over 517 Educators and Supervisors. This network has reached 31,000 villages and 42 million customers, as well as 22,000 doctors and 18,000 pharmacies. It is currently re-evaluating its program and hopes to be able to reach 100 million customers within five years. Part of its expansion strategy includes discussions with state governments for long-term support. They currently have agreements in place with three state-level authorities in India (Dehekar, Meghdoot, personal communication, April 15, 2013).

7.2 Licensing Agreements: Gilead Sciences, Inc.

Gilead has taken a different approach to reaching BoP markets, by partnering with local generics manufacturers to release patents for their HIV/AIDS treatments for a minimal licensing fee, and by supporting domestic health education efforts.

Gilead is an established pharmaceuticals manufacturer in the USA and a global market leader for HIV treatments. In 2009, it earned the top spot on BusinessWeek's top 50 companies, with sales growth over 38% for the last three years, and 44% return to shareholders over that same period. It was the first branded manufacturer to develop and launch once-daily pill antiretroviral drugs (ARV), Viread and Truvada, which greatly simplified the administration process for patients, and thus improved likelihood of adherence. Previous treatments required patients to take medication several times a day, to take several different types of medication, or both.

7.2.1 Pricing Scheme

Gilead's Access Program uses a dual channel model to serve developing countries. In one channel, they partner with 11 distributors to sell their branded products in 130 lower-middle-income countries. These distributors are permitted to add a 10 to 15% markup to cover the costs of registering the products in their own countries, manage local logistics and educate the local medical community. Gilead prices their drugs in this segment between \$30 and \$45.

In the other channel, they license generics manufacturers in India to produce generic versions of their drugs for 94 low-income countries (defined as those with gross national income per capita below \$1000, according to the World Bank) with high HIV prevalence. The licensees pay a 5% royalty on their sales, and are allowed to set their own prices. Gilead also chooses to offer non-exclusive licenses, in an effort to further drive down prices across the market (Lee, Rangan 2011).

7.2.2 Product Registration

Early iterations of the Access Program had revealed the difficulty in expanding reach in new markets without meeting product registration requirements in these countries. Initially, Gilead had tried to reduce costs by using import permits like those mentioned in earlier sections, to get their ARVs into the country. These permits were constrained however, to a limited amount, time frame, and use of the drugs (i.e. targeting a specific end-user). This also meant that Gilead was not able to hold stock of the drug in the country either. As a result, they were only able to reach 100 patients in their first year.

This poor result pushed Gilead to apply for product registration, which allowed full distribution and marketing opportunities. They standardized their registration dossier as much as possible to reduce costs, before sending it to their partners in each country. The importance of in-country partnerships are thus critical to Gilead's success.

7.2.3 Partnerships

Gilead depends on their local distribution partners to seek product registration, educate consumers and market their product, and manage their local supply chain. These partners have a deep and valuable understanding of the local context. This partnership model also saves the costs of building their own facilities. To support their efforts, on top of the 10 to 15% markup permitted, Gilead also offers a budget to support educational efforts in the country. On top of their 11 distributors, they also have access to a network of 48 local sub-distributors, forming a global network covering 130 lower-middle-income countries.

One of the challenges Gilead faces with distribution of ARVs is demand forecasting. Factors contributing to this challenge include complexity and inconsistency of funding options, changes in treatment guidelines, fluctuating political conditions, and a lead-time ranging from three to six months. To mitigate variability, Gilead focuses on expanding their relationships with organizations like CHAI and WHO, who have the ability to influence purchasing volumes and act as intermediaries between suppliers and distributors. Their partnership with the WHO is also important for meeting product quality requirements.

Their generics partners are required to obtain FDA approval or to be listed on the WHO PQM list, to meet international standards. This tedious process might cause hesitation from their partners; to a certain extent, Gilead tries to mitigate this by seeking certification for the branded version of the products, in which case the generics partners are only required to prove bioequivalence.

7.2.4 Education and Marketing

Education is a key aspect of Gilead's Access Program. They focus on educating distributors on HIV/AIDS, ARV products, safety reporting and the company's anticorruption policies. They also leverage their relationships with thought leaders to obtain educational resources and materials. Their partners in turn are responsible for conducting regional healthcare education programs, and educating local healthcare providers and governments on the safe and effective use of their products. Gilead supports their efforts with an allocation from their own budget (Samuel, Clifford, personal communication, April 9, 2013).

7.2.5 Reach

As of 2012, Gilead has reached 3.5 million patients in developing countries through their Access Program, and has licensing agreements with 15 Indian generic companies. Their sales through this program make up 70% of total sales. They have expanded their program to include treatments for Hepatitis B and Visceral Leishmaniasis, and hope to have six to eight million patients on their treatments in the next two years (Samuel 2013).

7.3 Global Pharmaceuticals Partnerships: ViiV Healthcare

The last business model example considered is ViiV Healthcare, a joint venture between Pfizer and GSK, established in 2009 and focused exclusively on the development and distribution of HIV treatments globally. Both businesses have contributed their entire HIV arms to the venture, with GSK taking 85% ownership and Pfizer 15% (Butler 2009).

The company works exclusively on research, development and commercialization of HIV treatments and builds on earlier work to combat HIV by combining the existing HIV portfolios and pipeline of both companies. ViiV Healthcare's goals are to deliver advances in treatment and care for people living with HIV, create new approaches to delivering new and more effective HIV medicines, and support communities affected by HIV. Their initiatives focus on four areas: education, support services, local healthcare capacity and capabilities, and reducing stigma and discrimination (ViiV Healthcare 2012).

7.3.1 Funding

ViiV Healthcare is funded through sales of 10 available medicines, previously belonging to Pfizer and GSK, which generate annual revenues of \$2.28 billion USD. This revenue provides funding for their initiatives, and funds R&D efforts for new drug developing, sponsored by ViiV Healthcare and executed by groups at Pfizer and GSK.

7.3.2 Pricing

ViiV Healthcare follows a two-tier pricing scheme based on the development index of the purchasing country. For the governments, non-profits and donors in low-income and least-developed countries, ViiV Healthcare offers non-profit pricing, and distributes their drugs at no profit to them. They also voluntarily release licenses for their ARVs, royalty free, to generics manufacturers.

For middle-income countries, of which India is one, ViiV Healthcare uses a flexible pricing model that takes into account the country's GDP and impact of HIV on the country. They also engage governments in an effort to reach affordable prices, and to scale their other efforts to reduce the HIV footprint. In some cases they also work with local in-country partners to manufacture their drugs at lower costs (ViiV Healthcare 2012).

7.3.3 Profit Sharing

Profits from successful combinations are shared between the two parent companies, in proportion to their contribution of active compounds (Butler 2009).

In each of these models we have seen unique approaches for overcoming challenges in reaching BoP markets, including last-mile delivery, education, and low-cost manufacturing. Novartis' decision to take individual ownership of last-mile delivery means they have control of the supply chain and can easily make modifications. Gilead has been able to grow their Access Program quickly by partnering with generics manufacturers, who in turn have far-reaching distribution channels and the ability to produce low-cost versions of their drugs. Similarly, ViiV Healthcare has invested capital from two global pharmaceutical companies to offer a larger portfolio of drugs, while at the same time supporting local efforts to improve health education and build capacity. In the next section we will compare the effectiveness of each of these approaches in overcoming not just last-mile delivery, education and low-cost manufacturing, but other common challenges for multinational business at the BoP, as described in section 3. This will also set the stage for a discussion on their potential to address other gaps in the delivery of healthcare in rural India.

8 Comparative Analysis

To be able to evaluate these different models effectively, we need to create a common comparison framework. A comprehensive evaluation requires consideration of both the long-term business value as well as the health improvements realized by the consumer. Therefore, we look to answer two important questions: how sustainable and scalable is this model in the long run, and what is the benefit to the end-consumer? Below we describe the measures used for each, and their significance.

8.1 Sustainability and Scalability

When addressing issues of sustainability and scalability, it is most effective to look at the key business features of the model. For example, we would expect that a model that is financially self-sufficient shows the greatest promise of being sustainable. When we discuss scalability, we refer to the potential of the model to expand into more rural markets. This might be reflected in current volumes and future targets, but also the long-term vision for the program. Here we discuss bottlenecks in achieving scale at the BoP from section 3, and describe the techniques that have been employed by the businesses described above to address them.

8.1.1 Human Capital Management

One of the unique challenges in reaching the BoP is addressing the needs of highly localized and separated communities. Doing so often requires employing higher volumes (in comparison to developed markets) of local talent that is connected and trusted, but may not have the skills needed. As a result, heavy investment in training is required. Retention efforts also need to be higher than usual, since pre-trained BoP employees are rare and lucrative for many companies looking to enter the market.

This challenge is addressed in different ways by the business models, though they all choose strategies that remove personal responsibility for handling the issue. For Novartis, all their AP human resources (HR) programs are managed by a third party recruiter, partly because the expertise does not exist in-house, and partly because book-keeping standards set limits on the budget amount that can be allocated to

HR. Gilead leaves BoP HR concerns to the responsibility of their local generics partners, as does ViiV Healthcare.

The benefits of “outsourcing” the HR function are clear, but as a tradeoff these companies relinquish control and potentially effectiveness. Gilead for example, has little understanding of the actual reach of their products: that is, whether their partners are actually able to get the drugs to the BoP and if so, how much and how effective it is. The cost savings and control/effectiveness tradeoff is a common theme in the other business aspects described in the following sections.

8.1.2 Marketing and Distribution

Marketing in rural markets is critical. As these markets are thought to be uneducated and disconnected from formal means of communication, traditional methods of marketing do not apply. Brand recognition is much lower and hence less of a consideration in purchasing decisions. As such, there are two important activities that businesses looking to establish themselves in rural markets must undertake. First, they need to educate these markets on the importance of healthcare and the options that are available to them. This is done with the aim of creating demand for their products. Second, they need to work with local doctors and pharmacies to stock their products, to address this demand.

The costs of last-mile delivery are often prohibitively high, and similar to HR, outside the strengths and expertise of these pharmaceuticals. The decision to invest is often strategic, and tied to a longer-term vision. Of all the models considered, only Novartis’s Arogya Parivar makes the effort to travel out to the communities to distribute their medicines. Others rely on their partners, whether generics manufacturers or non-profits, to manage distribution. To compensate for this cost allocation, they offer discounted pricing and/or licensing. In the short-term this has the power to boost production and potentially distribution, though the pharmaceuticals have no existing mechanisms to track this.

8.1.3 Partnerships

In almost all scenarios, the costs of providing medicines to rural markets, whether in branded or generic forms, is unprofitable. This can be mitigated through partnerships with international procurement agents,

and other third-party players who subsidize costs so they can be affordable. Government is also a possible partner, and in most models that are looking to scale, the desired option in the long-term.

As we saw in the previous section, partnerships can exist between two for-profit entities (e.g. Gilead and ViiV Healthcare partnering with generics manufacturers), between a for-profit and non-profit (e.g. ViiV Healthcare partnering with local organizations for outreach or Gilead's partnerships with CHAI and WHO) and between a for-profit and the government (e.g. Novartis engaging state governments to support their program). Some provide a critical support structure to fill infrastructure and network gaps in the short-term, while others are aimed at the long-term sustainability and scalability of the program. Long-term partnerships often require a greater amount of up-front discussion and negotiation, and are often overlooked in favor of partnerships that are beneficial in the short-term. This tradeoff and possible mitigating strategies are discussed in the next section.

8.1.4 Product Mix

An important consideration in these markets is the type of product to be distributed. Generics tend to be much more affordable, but branded products might still be chosen in some scenarios because of their brand value. Agreements between multiple pharmaceutical manufacturers, both branded and generic, are often formed with the objective of expanding the product portfolio, and improving development capabilities. However, we see that many partnerships tend to focus on a single type of medicine, including anti-diabetics and HIV treatments, as is the case with Gilead and ViiV Healthcare. This can be influenced by external factors, including access to funding from third parties such as the WHO, who are driven to invest in projects aimed at meeting certain objectives, most notably the Millennium Development Goals. Medicines that are listed on the WHO List of Essential Medicines also tend to have fewer country-specific requirements. As the costs of acquiring certification in a particular country are substantial, this can be a significant influencer in product decisions as well.

Companies like Novartis that choose to develop and market products on their own on the other hand, have more freedom and control over the portfolio of products they can offer. This gives them greater flexibility

in designing a mix that they feel matches the demands of their customers, but at a potentially higher cost. Current baskets range from a single product to complementary non-medicinal products that are also needed in these markets, and can help to boost sales of local doctors and pharmacies.

Packaging is also an important consideration, not just for the end-consumer, but also for the manufacturer. Smaller packages for example, such as those being used by Novartis, are more attractive to consumers, though this may increase incremental packaging costs for the manufacturer. It is also important for manufacturers to distinguish their branded drugs from the generics. This differentiation can be made between the drugs themselves (e.g. shape, color), and/or in their packaging. Both strategies are practiced by Gilead. Control of packaging and unique labeling also helps to distinguish products from possible counterfeits.

The last challenge that can influence product decisions is demand forecasting. For several of the reasons described earlier, particularly lack of infrastructure and communication, demand forecasting can be especially challenging. One incentive for country certification is the ability to hold stock of a particular drug in the country, as opposed to parallel importing, which can only be done for a specific purpose. Manufacturers attempt to compensate for this lack of information by building partnerships with procurement agents such as CHAI. These types of organizations are also working to provide accurate demand forecasts, to encourage production.

8.2 Patient-Focused Measurement

While almost all of the models considered in this analysis had addressed the issues above in some way, it was much more difficult to find information on the improvements in patient outcomes. The businesses use volumes (either in sales or in patients reached) as a reflection of their impact, but it is not clear whether accessibility alone drives improved health incomes. There are aspects of delivery and administration that are also important, but often considered out of scope for pharmaceutical manufacturers.

To provide a framework for evaluation, we look to Michael Porter's value-based approach to global health delivery. Rather than focus on maximizing volumes and profits, Porter urges the design of a system that focuses on the delivery of improved health outcomes, measured in health outcomes per dollar spent. In this way, the objective becomes better health, rather than better treatment (Porter 2010). For this form of measurement to be effective, it is critical to understand the entire health cycle for a particular condition through its six stages: monitoring and prevention, diagnosis, preparation and intervention, recovery and rehabilitation, and ongoing monitoring and disease management. Then for each of these steps it is important to understand the key health measurements and indicators, the relevant providers, the necessary actions and the products and services required. This information will help providers make decisions on what interventions are best, and where they should be placed. In order for this model to work, providers need to be incented and equipped with information to deliver the best possible health outcomes rather than profits alone. As such, businesses that are founded on this principle and tie their financial success to the health outcomes of their patients are more likely to succeed.

8.2.1 Application to Pharmaceuticals

Typically, pharmaceutical manufacturers have been driven to maximize profits by delivering new medicines that are used only in the latter stages of the value chain. However, given their understanding of the health delivery spectrum and access to capital, they are in a unique position to scale up their impact and improve overall health outcomes. In some cases we see organizations like ViiV Healthcare moving into the earlier stages of the cycle with health education and outreach. Some, like Novartis, have ventured into the distribution of their medicines, while others, like Gilead, have opted to use non-exclusive licensing as a way of stimulating competition in underserved markets. Product development that focuses on simplicity in administration is also valuable. While these actions have gone a long way to improve health delivery and outcomes however, there is still room to grow.

Understanding complementaries for example, provides new opportunities for valuable intervention. Maternal and child health services can help to reduce incidence of HIV and AIDS transfer from mother to

child. Community Health Workers are in a good position to ensure compliance with ARV therapy, but can at the same time address other health conditions (Rhatigan, Jain et al. 2009).

For each of the business models considered, we evaluate not only their current effectiveness according to the care delivery value chain, but also the opportunities for them to extend their model to improve health outcomes for their target consumers.

Typically, pharmaceutical manufacturers tend to focus on the intervention stage of the care delivery value chain (CDVC). Their profits are dependent on the sale of their medicines, which in turn relies on there being a population requiring treatment. As a result, they focus on the development of effective and affordable drugs, and on close relationships with their sales channels (i.e. doctors).

In contrast, based on the new business models described above, we are starting to see an increasing amount of focus being paid to health education. It may be driven by the need to create a market for their products, by social responsibility-related initiatives, or both. The sections below describe the different approaches being taken by each of the models described in section 0.

8.2.1.1 Monitoring and Prevention

There is an increasing focus on monitoring and prevention; benefits to these pharmaceutical players include the creation of a new market through education, and a better understanding of their demand patterns in later parts of the cycle. We see however, that only one of these models, the ViiV Healthcare partnership, invests in preventative education.

Gilead invests in educating the medical and clinical advisors on the proper use of their medicines. Arogya Parivar uses its Health Educators to teach consumers about different types of diseases, and the possible treatments. Doctors are taught about Novartis' different products and their uses. It is only with ViiV Healthcare that we see an investment in preventative education. They invest in partnerships with non-profits, such as the Public Health Research Institute of India, which educates would-be mothers on the importance of reducing mother-to-child transmission.

It might be argued that education in general is beneficial, as it raises awareness and could improve preventative efforts. But at this point the relationship is unclear, and one that the pharmaceutical manufacturers are striving to make more explicit. Novartis for example, is looking to implement a referral card system for Health Educators to give to patients, which they can then pick up from doctors and pharmacies. While this should give them some sense for the effectiveness of their education program in generating sales, it is difficult because of many external variables. Some patients for example, may forget to bring their cards and be re-diagnosed. Others may not go to a distributor right away. Both these behaviors would skew any numbers.

8.2.1.2 Intervention

Intervention is the typical point of interest in the CDVC for pharmaceuticals, and continues to be the case for the models described above. In a rural and impoverished setting, there is the greatest complexity in this area. Multiple parties, including those described in earlier sections, have interests in delivering the most effective drugs to these markets. The inclusion of subsidies and government buyers morphs the market significantly, but we can see that despite this, pharmaceutical players continue to invest their efforts to developing their competitive advantage in this area.

Novartis distributes a portfolio of drugs to local doctors and pharmacies through their Sales Supervisors, who are also responsible for teaching the proper administration of these drugs. Gilead's Access Program was founded on the development and distribution of their HIV drugs Viread and Truvada, and has since expanded to include treatments for Hepatitis B and Visceral Leishmaniasis, the world's second-deadliest parasitic disease. ViiV Healthcare was formed solely for the discovery and distribution of HIV drugs.

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9 Discussion

We see from the analysis above that pharmaceuticals are involved only in a limited number of steps in the CDVC. Recognizing that the rural market is still unrealized and that the population is largely uneducated on health matters, companies are supplementing their intervention efforts with education, in order to improve demand. It is unclear however, whether those educational efforts are helping to drive demand. Some organizations such as Novartis are attempting to put in systems to monitor their effectiveness. Their methods are ineffective however, as there are high levels of inconsistency in the actual delivery of their referral cards.

Education is not the only lacking element in these new markets. In fact, businesses have had to take novel approaches to circumvent some of the major challenges in reaching rural developing markets, including human capital management, sales and marketing, product development, and supply chain management. The approaches taken in the increasingly competitive developed market often are not replicable in BoP markets, and attempts at doing so can be wildly unsuccessful, as they do not reflect the realities described earlier, such as lack of basic infrastructure and access to capital. But we can see from the stark differences in approaches taken thus far, that there is no clear direction on the best path forward. As a result, the benefits and challenges of each approach vary as well.

In the short-term, for example, partnerships and subsidies provide a way of relieving some of the more onerous costs of purchasing and distribution to rural markets, which are normally beyond the expertise of pharmaceuticals. Licensing agreements provide a means for these manufacturers to leverage their drug development strengths to release their drugs to the market, without bearing the costs of distribution themselves. Joint ventures between pharmaceuticals help to relieve similar costs, and separate the costs of new market research and development from the parent organization. Subsidies and supply chain support provided by third parties help incentivize drug development and relieve costs of distribution, which can otherwise be prohibitive.

In the long-term however, these models are subject to instabilities. These partnerships and agreements are initiated to mitigate short-term weaknesses, but as the economies of developing markets mature, the strengths of these arrangements will dissipate, and pharmaceutical companies will be forced to compete on factors similar to those in developed markets. In this way, these structures are only temporary fixes to a much larger problem that when resolved, will leave the companies in a weaker position, compared to those who took steps to invest in being a part of the development of these markets from the start. Though costs are considerably higher, the expected longer-term payoff and opportunities to leverage that infrastructure for other means can strengthen the business appeal.

If we consider the CDVC for example, we have already noted that there are only a few elements along the chain where pharmaceuticals tend to focus their efforts in developing markets: namely, prevention and monitoring (to a very limited extent), and intervention. However, developing markets lack support for many of the other steps in the chain as well. In the short-term view, pharmaceuticals focus only on mitigating the weaknesses in the intervention stage and more precisely, in the demand for the treatment. They have taken numerous approaches to doing so, and the extraordinary focus on this aspect by non-profits and multilateral organizations has created a highly complex ecosystem that attempts to promote the best interventions. The response from pharmaceutical manufacturers shows that there is great interest and progress in drug development and distribution. It is not clear however, whether this alone is enough to improve health outcomes for developing markets. From the perspective of the CDVC, we see that there are many steps in care delivery that are lacking in developing markets; treatment alone will not be enough to improve overall health outcomes. The opportunities to mitigate the challenges in the other steps of the CDVC provide both a challenge and an opportunity for pharmaceutical companies to establish a sustainable competitive advantage.

Global pharmaceutical companies are in a unique position where the incentive to move into developing markets is on the rise, both from a commercial and social angle. They are also facing increased pressure to identify new sources of revenue as the “patent cliff” approaches. With their current access to capital and support from third parties, market knowledge and understanding of the “best” health delivery models,

they are well positioned to develop systems to support the development of the other parts of the CDVC. Doing so will not only present other market opportunities, but will also help to form a system that delivers better health outcomes.

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10 Recommendations

From the information presented and the discussion above, we can see that delivery of health in rural markets is a significant challenge and opportunity for global pharmaceutical manufacturers. Each of the approaches taken by the organizations discussed above is a different attempt at maximizing impact and profit in these underserved markets, each with its own strengths and weaknesses. In this section we discuss the ways businesses can incorporate the strengths of each of these models, and the ways they can push further to deepen their involvement with the health delivery chain.

10.1 Short-Term Recommendations

10.1.1 Leverage and Expand Partnerships

In the short term, it is important for these companies to recognize the existing infrastructure in reaching these markets, and to leverage those relationships to extend their reach. From the literature we saw that securing trust is a critical attribute in serving these markets, and that connecting with trusted leaders in these communities is one way to do so. Working with non-profits to identify a local sales force is a way not only of earning the trust of these communities, but also of addressing human capital concerns in expanding reach. These partnerships also present an opportunity to improve educational efforts, whether from a prevention or treatment perspective.

Another important infrastructure to recognize and leverage is that surrounding the treatment of diseases such as HIV/AIDS, malaria and TB, which have earned the attention of international non-profits and multilaterals. Here there are several opportunities to incorporate donor funding to offset costs of delivery, which can help to fund exploration into other growth areas, some of which are discussed below. Companies should also aim to have their medicines added to the WHO List of Essential Medicines or PQM list, to facilitate country purchasing and distribution decisions.

The last network that pharmaceutical manufacturers should recognize is that of local generics manufacturers. Given their strength in affordable drug development and extensive networks in the

country, as well as the growing demand in these markets, partnerships in this area also present an opportunity to extend market reach, to access expertise in drug development, and to learn about the specifics of working in the Indian market. Though the specifics of any partnership will be nuanced depending on the skills and expertise that both parties can offer, the resulting benefit to both parties could set up a structure for improved drug delivery not just in rural markets, but globally.

10.1.2 Accumulate Knowledge

While making use of these partnerships to expand market reach, pharmaceutical manufacturers should also take advantage of these opportunities to improve their overall understanding of the health delivery landscape, and investigate opportunities to grow in new ways. Funds that would normally be allocated to product development and distribution, for example, can be reassigned to R&D for new market opportunities.

From their non-profit distribution partners for example, these companies can learn about the other challenges that exist locally in healthcare delivery. They can identify needs not only for other medicines, but also for technologies and tools that are lacking. They should also evaluate whether their drugs are being administered at the correct stage of intervention, and if not, if there are other opportunities for them to change their target consumer, or to provide more effective medicines. Given their medical understanding of disease patterns, they can also use this opportunity to distribute treatments for diseases that often occur together, such as HIV/AIDS and TB. Lastly, they can use information on sales patterns to understand which of their products are in higher demand, and tailor their supply accordingly.

For diseases like HIV/AIDS, malaria and TB, pharmaceutical manufacturers should use the specific opportunities they have in these areas to extend their involvement in the value chain from just treatment to other areas, including monitoring and prevention, and diagnosis. Given the extensive focus on medicine delivery, companies should leverage these subsidies to explore opportunities in other areas. Preventative measures for example, such as the use of condoms to prevent the spread of HIV/AIDS, or mosquito nets to prevent malaria present market opportunities also in need of investment and for-profit

intervention. These needs are also ongoing and therefore could offer more lucrative business opportunities down the road.

Partnerships with generics manufacturers offer the opportunity to accumulate knowledge on the specifics of the Indian market, including customer preferences and local epidemiology. They also have the opportunity to learn about the low-cost manufacturing process and sales force management. With the “patent cliff” looming, this knowledge may prove highly lucrative in the coming years, as more pharmaceutical manufacturers look to extend the reach of their existing drug portfolio.

10.2 Long-Term

10.2.1 Customize Product Offering

In the long term, given the accumulated understanding and integration into the rural healthcare system, pharmaceutical companies are well positioned to offer customized packages to fit the needs of their consumers. Beyond simply customizing drug packages like Novartis is already doing, these organizations should leverage their position to offer complete healthcare packages that encompass products and services along the CDVC. This approach ensures continuity in care provided along the chain for a given disease.

For HIV/AIDS for example, Gilead has already established itself as a market leader in the development of treatment drugs, and is heavily engaged in educational efforts with public health administrators. There is an opportunity for them to extend their HIV/AIDS coverage even further by connecting with communities to engage in preventative education and action, and to provide support to the health providers in continued monitoring of their HIV/AIDS patients. In doing so they improve their relationships with these providers, which could provide other opportunities for sales in the future. They also prevent competitors from attempting to use these other channels to steal customers away, and guard against counterfeits.

From the other perspective, Novartis has already built relationships with local providers and suppliers and provides them with a variety of drugs and other medicines, both for treatment and prevention. They should focus on those diseases for which treatment and other steps in the CDVC are most lacking, and where demand is high. They can leverage the trust they have earned from the local communities to

distribute other goods needed to delivery care to these patients, including diagnostic tools and training, as well as reagents and other medical consumables, among others. This presents opportunities for them to partner with other health commodity providers to address multiple shortages in supplies needed for health delivery.

10.2.2 Open Channels to Complementaries

Having an established infrastructure along the spectrum of care also provides an opportunity for these companies to improve quality of care by recognizing what other diseases might be treated or services could be offered at similar stages. Since HIV/AIDS and TB often occur together, they can be diagnosed at the same time. This means that Gilead could open its distribution and education channels to other players who are looking to raise awareness about TB, if they do not have the ability to develop treatments for that particular disease in-house. In these cases they are essentially licensing out their networks to other manufacturers who have chosen to focus only on drug development.

These channels can also be exploited to distribute health-related goods that may not be tied to a specific disease, but rather to a specific provider. Novartis for example, can use their connections to rural primary healthcare providers to offer other products or services that are most effectively administered at that level. These might include simple things like nutritional supplements and oral rehydration salts, for example. Again, establishing the distribution channels at each stage along the CDVC provides an opportunity to bring in additional income through agreements with other parties.

10.2.3 Government Engagement

Pharmaceutical companies acknowledge that subsidies are not a long-term solution, and believe that government support is necessary to support and scale up the solution. This is partly driven by the belief that the government should support health programs, and also by the fact that many communities are still unreachable in a financially sustainable way. Whether or not the Indian government will have the capacity and willingness to do so is another question. But if companies are aiming for government support in the long-term, they should be engaged in discussions from the start, to ensure they are aiming for the same

goal. Examples like Manila Water in the Philippines show that private intervention of necessary goods and services can be scalable and successful with proper government support from the start. Stating the intent later is less likely to be able to secure the desired support. In even worse cases, the government may view these privately run programs as a threat to their existing network, and may take steps to stop the program from expanding, as was the case with Catholic University's Ancora project in Chile.

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11 Conclusion

Though often demonized in the world of healthcare and scrutinized for their profit-chasing strategies at the expense of actual health advancement, we have seen in this paper that global players in the pharmaceuticals industry are beginning to recognize the limits to their current mode of business, and are exploring ways of expanding their reach in new markets. Given the rate of economic growth in India and specifically the demand for quality care, it comes as no surprise that more and more international players are testing new methods to deliver their products to previously underserved markets in rural India. Doing so however, requires overcoming a lack of basic infrastructure, insufficient access to capital, and low levels of health education and product awareness. They also enter into a highly complex ecosystem, where long-standing generics manufacturers have dominated with expertise in low-cost drug development and established local distribution channels. Non-profit organizations, from the highly local to multilateral, have also found a role for themselves, filling information and funding gaps along the supply chain. These mechanisms serve a fickle dual role of both incenting global pharmaceutical manufacturers to contribute their latest and most effective drugs, while simultaneously insisting on the lowest possible purchasing price. Given this difficult position, the desire for pharmaceutical manufacturers to try new methods seems inevitable.

Some have chosen to pursue individual strategies, investing in human capital-intensive decentralized distribution channels and customized packaging to meet the needs of their customers. Others have formed partnerships with non-profit, governmental and other for-profit entities, in hopes of leveraging complementary strengths to compensate for the weaknesses listed above. In all cases, there is an acknowledgement that education is critical, both to build product awareness and literacy, and to improve demand. In short, these companies are faced with the challenge of building up the market they hope to serve. In the short-term, these companies have an opportunity to leverage subsidies and other forms of support to offset the costs of drug development and delivery. Whether they have the vision to use these advantages to pursue opportunities for long-term growth however, will be a critical factor in determining

which of them can improve and sustain their competitive advantage. Drug development alone will not be enough, especially in these markets.

Rather than ignore these challenges however, pharmaceutical manufacturers should strongly consider how their accumulated expertise in healthcare delivery could create a long-term market opportunity in rural India. Given the lack of reputable options both in the public and private sector, and major gaps along the health delivery spectrum, these companies are in a good position to extend their business model to include all elements along the CDVC, whether for a specific curable disease, for enduring prevention strategies, or for on-going treatment and monitoring of chronic diseases. All these avenues serve to improve the state of health in these communities, while also opening up a new market. In this way, the seeming tension between profit and social value does not need to endure. This paper was written with the intention of discussing the potential for global pharmaceutical manufacturers to prove just that. Exploring opportunities in the CDVC opens the potential for global pharmaceutical manufacturers to completely change the way they do business not just in India, but in other BoP markets around the world. Some have already started exporting these models and the low-cost drugs manufactured by their generics partners to other developing markets. And while scale continue to be a priority, these companies should continue to innovate and consider other opportunities to grow their footprint. Glocal Healthcare, for example, operates five hospitals offering primary and secondary healthcare services to rural populations in West Bengal (Glocal Healthcare 2013). This could offer a new outlet for distribution, as could other grassroots-based health enterprises. Mobile penetration also presents an opportunity to extend educational efforts and increase demand. Jacaranda Health, a social enterprise offering maternal and newborn healthcare services in peri-urban Nairobi, is piloting an mHealth innovation called “Baby Monitor.” The program instructs expectant and postpartum mothers to report personal health indicators that may signal the need for further attention (Ettenger 2012). Similar approaches could be used to encourage regular checkups, or adherence to treatment schedules. These are only a few ideas that, with the support of global pharmaceutical capital and knowledge leadership, could grow into financially sustainable and scalable models for improved health in BoP markets around the world.

Though these global pharmaceutical manufacturers are facing the undeniable pressures of increased demand for low-cost drugs and an impending “patent cliff”, they also have an opportunity to pursue truly disruptive and innovative models for health delivery in BoP markets that, while improving health outcomes, could also become new channels for sustainable revenue generation. The question for each of them then becomes how much they are willing to invest in these opportunities, and how much risk they are willing to bear, given their increasingly constrained financial conditions. Those who make smart investments and nurture their consumer base across the entire health delivery spectrum will position themselves to be leaders in these rapidly developing markets, who are sorely in need of reliable health delivery options.

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